Electromagnetic Compatibility – How to Promote EMC

FDA/FCC Public Meeting: Converged Communications and Health Care Devices Impact on Regulation

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Rick Hampton
Wireless Manager
Partners HealthCare
Information Systems

Faulkner Hospital

Spaulding Rehabilitation Hospital

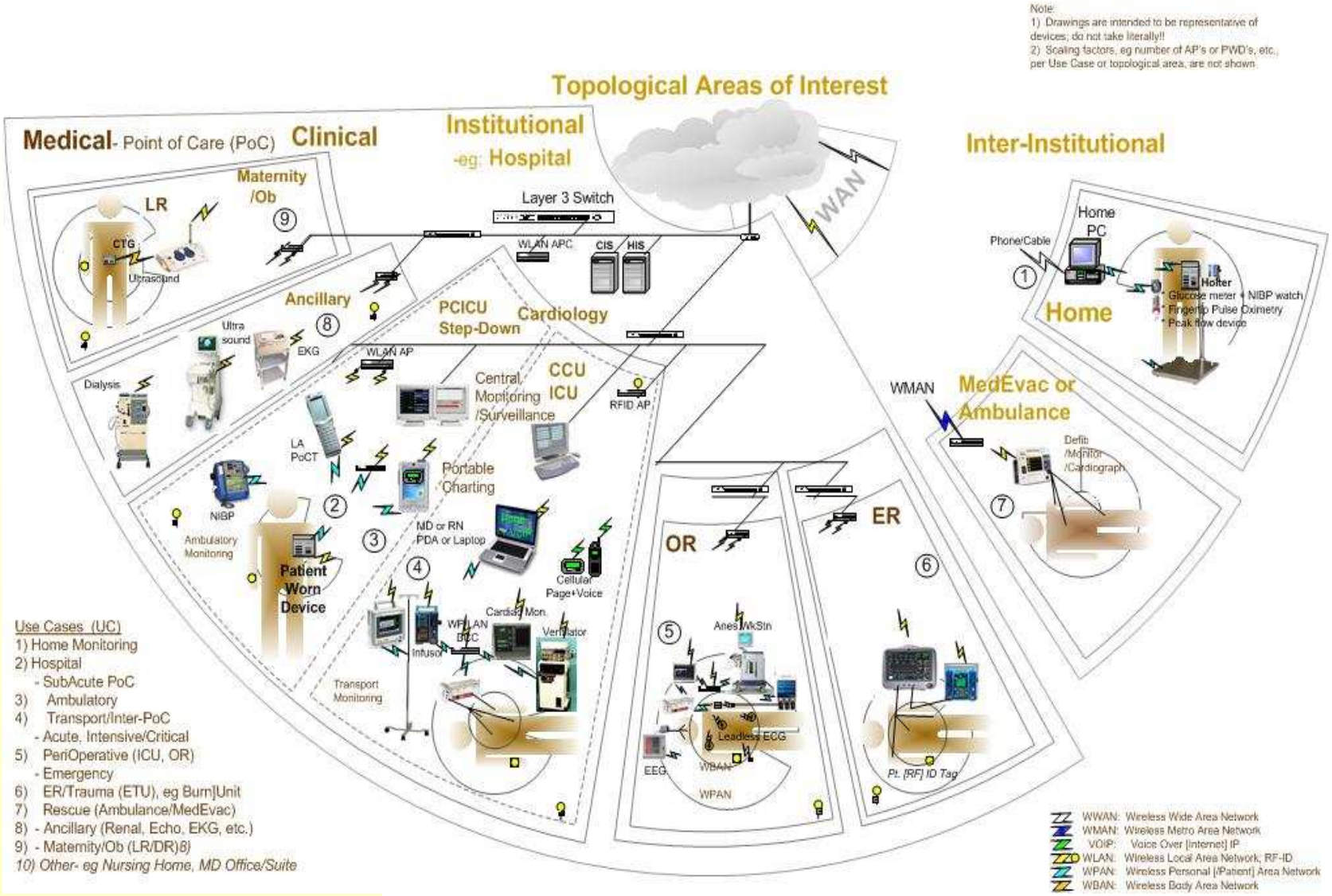
FCC Services Utilized

- ISM (Industrial, Scientific, Medical)
- WMTS (Wireless Medical Telemetry Service)
- PLMRS (Private Land Mobile Radio Service)
  - Public Safety
  - Bio-medical Telemetry
  - Industrial/Business
  - Private Land Mobile Paging
  - Radiolocation
- Paging
- MURS (Multi-Use Radio Service)
- FRS (Family Radio Service)
- GMRS (General Mobile Radio Service)
- MICS (Medical Implant Communications Service)
- Part 15
  - Medical Telemetry
  - RFID
  - Spread Spectrum
  - U-NII (Unlicensed National Information Infrastructure)
  - UWB (Ultra WideBand)
    - Medical Imaging
- Cellular Radio Service
- SMRS (Specialized Mobile Radio)
- AWS (3G) - Advanced Wireless Services Spectrum
- PCS (Personal Communications Service)
- Amateur Radio
- Private Operational Fixed Microwave

IEEE p1073.0.1.1

Use Cases - Overview

31Aug04 Rev 3b



Courtesy Jan Wittenber, Philips/IEEE 11073

EMC and Interference

- Electromagnetic compatibility (EMC) broadly deals with interactions between electronic devices
- Focus on Harmful Interference
  - FCC Definition: "…Interference which endangers the functioning… or seriously degrades, obstructs, or repeatedly interrupts a radiocommunication…."

EMC Experiences

- Cell phones and patient ventilators
  - http://www.medscape.com/viewarticle/475203?rss
- TV vs. Part-15 Medical Telemetry
  - http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm127778.htm
  - Some hospitals are still using Part-15 medical telemetry in “unused” TV channels
  - Initial conversations during a conference call with the IEEE Standards Coordinating Committee 41 ad hoc on White Space (WS) Radio indicates little knowledge of or concern with EMC and medical devices
- Analog AND Digital TV vs WMTS
  - http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm127780.htm

EMC Experiences – Cont.

- Bluetooth vs. WiFi
  - Bluetooth observed to cause WiFi outages within 5 meter radius
- Frequency Hopping vs WiFi
- WiFi vs. WiFi
  - WiFi vendor solutions cause some WiFi devices to loose connections and/or data, e.g. channel setting algorithms
  - Large, well-known academic medical center wireless network experienced major outages when adding half of 800 wireless IV pumps

Last Mile Problems

- Last mile problems include EMC if end devices are numerous
  - This includes healthcare facilities
  - This also includes multi-dwelling units
    - One of our CIOs has achieved mobility in her condo only with the aid of a 25’ CAT5 patch cable.

Underlying problems

- Over-marketing by vendors unfamiliar with medical devices
  - Claims of “interference-proof”, “medical grade”, and even “unlimited capacity” for their wireless technologies
  - Vendors shun risks, but will only acknowledge risks if required to comment
- Lack of management tools
- Limited ability for end customer to become knowledgeable and to act on risks

Recommended Solutions

- Formal, ongoing, working group between FDA and FCC, with input from expert stakeholders
  - Similar in nature to existing FDA Workgroups
  - May need to reexamine dedicated spectrum – E.g. MedRadio and MBAN

Recommended Solutions – Cont.

- Recognition of IEC 80001 Risk Management Standard – “Application of risk management for IT-networks incorporating medical devices”
  - Applies only to health providers – does not apply to individual/public use in home, at work, or on the street
- Recognition by ALL parties (hospitals, medical device manufactures, IT vendors, communications companies) that cooperation is required perform risk management and ensure wireless medical devices and systems are safe and effective.

References

- IEC 80001 DRAFT Risk Management Standard – “Application of risk management for IT-networks incorporating medical devices”, International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland, IEC web site http://www.iec.ch
- IEEE 11073, Part 00101: “Guide — Guidelines for the use of RF wireless technology”, The Institute of Electrical and Electronics Engineers, Inc., 3 Park Avenue, New York, NY 10016-5997, USA. Copyright 2008, PDF: ISBN 978-0-7381-5812-9 STD95835, Print: ISBN 978-0-7381-5813-6 STDPD95835

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- *C63.18, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters* – IEEE
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- *IEEE Std 473-1985, IEEE Recommended Practice for an Electromagnetic Site Survey (10 kHz to 10 GHz)* – IEEE
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Contact Information

Rick Hampton
Wireless Communications Manager
Partners HealthCare System
One Constitution Center, OCC210
Charlestown, MA 02129
Office: 617-726-6633
Cell: 617-968-2262
RHampton@Partners.org